

JUL 28 2000

K001378

**510(k) Summary  
Bionx Implants Inc.  
BioCuff™**

**Submitter's Name, Address, Telephone Number, and Contact Person**

Bionx Implants, Inc.  
1777 Sentry Parkway West  
Gwynedd Hall, Suite 400  
Bluebell, PA 19422

Contacts: Gerard S. Carlozzi  
President and Chief Executive Officer  
Phone: (215) 643-5000  
Facsimile: (215) 653-0984

Bionx Implants Ltd.  
Tuija Annala  
Quality Manager  
P.O.Box 3  
FIN-33721 Tampere  
Finland, Europe  
Phone: 358-3-316 5679  
Facsimile: 358-3-316 5688

**Date prepared:** February 4<sup>th</sup>, 2000

**Name of the device:**

- A. Trade or Proprietary Name: BioCuff™
- B. Common Name: Bioabsorbable soft tissue fixation fastener
- C. Classification Name: Bioabsorbable fixation fastener, soft tissue
- D. Device Product Code: MAI, class II

**Predicate Devices:**

510(K)	Trade or proprietary or model name	Manufacturer
1. K972783	1. SmartAnchor	1. Bionx Implants Inc.
2. K973849	2. Bankart Tack	2. Bionx Implants Inc.
3. K992567	3. Contour Labral Nail (Anatomical Bankart Tack)	3. Bionx Implants Inc.
4. K990361	4. Bio-Absorbable Corkscrew	4. Arthrex Inc.
5. K990987	5. Bio-Absorbable Corkscrew Suture Anchor	5. Arthrex Inc.
6. K990340	6. TissueTak	6. Arthrex Inc.
7. K973381	7. BioROC EZ	7. Innovasive Devices, Inc.
8. K992458	8. RC Multi-Suture Anchor	8. Innovasive Devices, Inc.
9. K984490	9. Sutureless Anchor	9. Innovasive Devices, Inc.
10. K963396	10. Biologically Quiet Biosphere	10. Instrument Makar, Inc,
11. K960555	11. Biologically Quiet Mini-Screw Suture Anchor	11. Instrument Makar, Inc,
12. K964805, K963369, K983186	12. Bio-Anchor	12. Linvatec Corporation
13. K990110	13. BioRC Anchor	13. Linvatec Corporation
14. K950272	14. Panalok	14. Mitek Surgical Products
15. K970896	15. Panalok RC	15. Mitek Surgical Products
16. K964013	16. Absorbable Toggle Anchor	16. Mitek Surgical Products
17. K911837	17. Suretac 6.0, 8,0	17. Acufex Inc.
18. K964921	18. De Puy Dupont Phantom Suture Anchor	18. DePuy Inc.

**Intended Use:**

The Bionx Implants Inc. BioCuff™ maintains proximity between soft tissue and bone to facilitate the soft tissue reattachment.

**Device Description:**

The BioCuff™ screw and washer combination is provided with a diameter of 5.7mm and lengths of 18, 28 and 36 mm with a spiked washer, diameter 8mm and thickness 3mm.

The BioCuff™ screw/washer combination is available with two versions, which are made of a poly-L-lactide homopolymer and poly-L/D-lactide copolymer.

**Substantial Equivalence:**

Properly used, in the presence of adequate immobilization, absorbable BioCuff™ screw/washer maintains proximity between soft tissue and bone to facilitate the soft tissue reattachment. BioCuff™ loses its strength over 20 to 50 weeks while the lesion of the tendon is healing. This indication is substantial equivalent with Bionx Implants Inc. SmartAnchor (K972783), Bankart Tack (K973849) and Contour Labral Nail (K992567) Arthrex Inc. Bio-Absorbable Corkscrew (K990361), Bio-Absorbable Corkscrew Suture Anchor (K990987) and TissueTak (K990340), Innovasive Devices, Inc. BioROC EZ (K973381), RC Multi-Suture Anchor (K992458) and Sutureless Anchor (K984490), Instrument Makar, Inc. Biologically Quiet Biosphere (K963396) and Biologically Quiet Mini-Screw Suture Anchor (K960555), Linvatec Corporation Bio-Anchor (K964805, K963369, K983186) and BioRC Anchor (K990110), Mitek Surgical Products Panalok (K950272), Panalok RC (K970896) and Absorbable Toggle Anchor (K964013), Acufex Inc. Suretac 6.0, 8.0 (K911837), DePuy Inc. De Puy Dupont Phantom Suture Anchor (K964921). Because no suture is needed for the reattachment of soft tissue to bone, some problems occurring with suture anchors, like suture breakage and the suture cutting through the tendon, can be avoided.

Also, like the predicate devices, the BioCuff™ is not intended for use in and is contraindicated for: 1) Insufficient quality or quantity of bone, 2) Foreign body sensitivity to the implant material. Where the material is suspected a test should be made prior to implantation to rule out sensitivity. 3) Patients with active sepsis or infection. 4) Conditions, which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing and rehabilitation period.

The BioCuff™ screw/washer includes an instrument set containing screwdriver, drill, grasper, bone tap, sterilization tray. The technological characteristics of an instrument set are identical with instrument sets, which are used with previously cleared Bionx Implants Inc. SmartAnchor (K972783), SmartScrew™ (K952471) and SmartScrew ACL™ (K993073). The only differences occur in diameters of drill and bone tap and

head of screwdriver, which are chosen according to dimensions and shape of product under consideration.

Biomechanical pullout forces of BioCuff™ and predicate devices are comparable and the devices are substantial equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Tuija Annala  
Quality Manager  
Bionx Implants Ltd.  
P.O. Box 3  
FIN-33721 Tampere  
Finland, Europe

Re: K001378  
Trade Name: BioCuff™ Bioabsorbable soft tissue fixation fastener  
Regulatory Class: II  
Product Code: MAI  
Dated: April 25, 2000  
Received: May 1, 2000

Dear Ms. Annala

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

*Danne R. Witten*

*SN* Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(K) Number (if known): K001378

Device Name: BioCuff™

### Indications for Use:

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(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

Dan R. Kochner  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K001378